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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,238	09/26/2001	Kristin Verschueren	4232.1US	1860

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EXAMINER	
CARLSON, KAREN C	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 02/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/964,238	VERSCHUEREN ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3, 8, 10, 12,18, 21, 22* is/are pending in the application.

4a) Of the above claim(s) *1,18 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,8,10 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/449,285

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

Applicant's election with traverse of Invention II, Claims 2, 3, 8, and 10 in the paper filed November 25, 2003 is acknowledged. The grounds of traversal and the Examiner's responses are:

Applicant urges that the pending claims were restricted in the parent application. As noted in the restriction in this application, the SMAD interacting proteins set forth in SEQ ID NO: 2 and NO: 4 differ in structure and in function and are therefore patentably distinct and subject to restriction. SIP1, SEQ ID NPO: 2 is 944 amino acids in length, the first 10 amino acids being MLTQGAGARK. SIP2, SEQ ID NO: 4 is 950 amino acids in length, the first 10 amino acids being MEEKEQLRRQ. Thus, the structures are different. SIP1 binds SMAD1, SIP2 does not bind SMAD1. Therefore, the functions are different as well.

Applicants urge that the pending claims comply with unity of invention and have a common technical feature. This application is not a national stage application of a PCT; Indeed, even the parent is a CIP of a PCT. Thus, unity of invention is not considered in this application. Also, as noted previously, the SMAD interacting proteins set forth in SEQ ID NO: 2 and NO: 4 differ in structure and in function and are therefore patentably distinct and subject to restriction, there being no unity of invention even under PCT rules.

Applicants urge that they have paid for an international search report and preliminary examination report in the parent application and are entitled to having more than one sequence examined. The parent application, 09/449,285 is not a PCT (nor a national stage application) and did not receive either an international search report or a preliminary examination.

Applicants urge that they have paid twice for the examination of the pending claims and refer to the parent application and instant application. In the parent, examination of claims drawn to nucleic acid were paid for, while in the instant application claims drawn to polypeptide (SEQ ID NO: 2) have been paid for. Thus, there is no overlap in e examination fees.

Applicants urge that they are entitled to rejoinder of the product and method of producing the product. The Examiner agrees. However, the scope of the product produced by the method of making the product must be the same or rejoinder is not possible. See the policy comments on rejoinder below:

> The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.
>
> In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The requirement is still deemed proper and is therefore made FINAL.

Upon search and examination of Invention II, it was determined that SEQ ID NO: 21 is a subsequence of elected SEQ ID NO: 2. Thus, there is no search burden for the Examiner to examine Inventions II and IV together and these inventions have been rejoined.

Claims 4-7, 9, 11-17, 19, 20, and 23 have been canceled. Claims 1, 18 and 22 have been withdrawn from further consideration by the Examiner because these Claims are drawn to non-elected inventions. Claims 2, 3, 8, 10, and 21 are currently under examination.

Priority is set to June 2, 1997.

The disclosure is objected to because of the following informalities: On page 1 of the specification, the priority and reference to sequence listing must be updated.

Appropriate correction is required.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2, 3, 8, and 21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The Claims do not recite that the polypeptide is isolated or purified, or acted on by the hand of man and taken from its original source. Thus, the claims are directed to non-statutory subject matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 8, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 depends from withdrawn Claim 1 and is therefore indefinite because, if Claim 2 is allowed, the process of Claim 1 will not be set forth in Claim 2. Further, the process is not complete, that is, how will one skilled in the art produce the SMAD interacting protein using a two-hybrid system described in Claim 1? How is a cDNA library going

to be a prey defining a polypeptide? Once a polypeptide is found, how will it be determined that it is a SMAD interacting protein?

Claim 3 is indefinite because it is not clear if Drosophila zfh-1 is a member of the zinc finger/homeodomain protein family or not. Further, it is not clear if the SMAD interacting protein of Claim 3 interacts with SMAD-5 or not. It appears that the claimed SMAD interacting protein of Claim 3 is indefinite because having different functions, that is, binding or not binding SMAD-5, will have different structures.

Claim 8 an 10 are indefinite because the function of the "functional fragment" is not defined, that is, what function should one skilled in the art be assessing to determine if they are in possession of a functional fragment of SEQ ID NO: 2?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, 8, and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 2 refers to a SMAD interacting protein determined by a process. However, no structure is provided for the SMAD interacting protein, thus lacking written description. Claim 3 refers to a SMAD interacting protein having a list of functions. However, no structure is provided for the SMAD interacting protein, thus lacking written description. Claim 8 refers to a functional fragment of SEQ ID NO: 2. The specification does not

provide written description of a fragment of SEQ ID NO: 2, or a function of the fragment. Thus, this limitation in Claim 8 lacks written description.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

On page 3 of the specification, Applicants admit that Zhang et al., Laguna et al., and Chen et al. are all prior art against their broadly claimed invention. Therefore, the following rejections are being made:

Claim 2 is rejected under 35 U.S.C. 102(a) as being anticipated by Zhang et al. (Sept. 12, 1996; Nature 383(168-172).

Zhang et al. teach hMAD-4 interacts with hMAD-3. Therefore, hMAD4 is a SMAD interacting protein because it interacts with hMAD-3. The reverse is also true, that is, hMAD-3 is a SMAD interacting protein because it interacts with hMAD-4.

Claim 2 is rejected under 35 U.S.C. 102(a) as being anticipated by Laguna et al. (Oct. 31, 1996; Nature 383:832-836).

Laguna et al. teach that SMAD-4 (DPC4) forms a complex with SMAD-1 and with SMAD-2 and is essential for SMAD-1 and SMAD-2 function. Therefore, SMAD4 is a SMAD interacting protein because it interacts with SMAD-1 and SMAD-2. The reverse is also true, that is, SMAD-1 and SMAD-2 are SMAD interacting proteins because they interacts with SMAD-4.

Claims 2 and 3 are rejected under 35 U.S.C. 102(a) as being anticipated by Chen et al. (Oct. 24, 1996; Nature 383:691-696).

Chen et al. teach that XMAD2 (SMAD-2) forms a complex with forkhead activin signal transducer –1 (FAST-1). Therefore, FAST-1 is a SMAD interacting protein because it interacts with SMAD-2.

Claim 2 effectively has no limitations other than the polypeptide be a SMAD interacting protein; thus, the references apply as cited. Claim 3 more specific functional limitations for the SMAD interacting protein claimed. As noted in Chen et al., FAST-1 does not interact with SMAD1, which is equivalent to XSMAD1 in yeast, and does interact with SMAD2. Therefore, the remaining 3 limitations of Claim 3 appear to be inherent properties of FAST-1.

No Claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Karen Cochrane Carlson Ph.D

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER